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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,131	12/05/2001	Geoffrey Goldspink	10103-004	8321

20583 7590 02/18/2004

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EXAMINER	
WOITACH, JOSEPH T	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 02/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/005,131	GOLDSPINK, GEOFFREY	
	Examiner	Art Unit	
	Joseph T. Woitach	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 July 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-96* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-96* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This application filed December 5, 2001, is a continuation of 09/403,707, filed March 17, 2000, now abandoned.

The original specification was filed with claims 1-30. Applicants' amendment filed July 31, 2002, paper number 3, has been received and entered. Claims 31-96 have been added. In Applicants remarks, it is indicated that claims 31-67 have been canceled (see amendment, page 10), however this inconsistent with the summary of the pending claims presented and the absent of these newly added claims beyond the preliminary amendment filed July 31, 2002. It appears that no claims 31-67 were previously pending to be cancelled and that newly added claims 31-67 should not be cancelled. For the sake of compact prosecution, the claims present in the Appendix are being used as the instantly pending claims. Claims 1-30 have been cancelled consistent with Applciants summary of the pending claims (see Appendix A, filed July 31, 2002, pages i-ix).

Claims 31-96 are pending and currently under examination.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 32-39, 41, 42, 49, 50, 51, 58-66, 68, 76-78 drawn to a method of treatment of an animal comprising administering a plasmid vector comprising a myosin light chain enhancer and a myosin heavy chain promoter operatively linked to a sequence that generates a therapeutic RNA, classified in class 514, subclass 44.

II. Claims 32-39, 41, 42, 49, 50, 51, 58-66, 68, 76-78 drawn to a method of treatment of an animal comprising administering a viral vector comprising a myosin light chain enhancer and a myosin heavy chain promoter operatively linked to a sequence that generates a therapeutic RNA, classified in class 514, subclass 44.

III. Claims 32-42, 49, 50, 51, 58-66, 68, 76-78 drawn to a method of treatment of an animal comprising administering a plasmid vector comprising a myosin light chain enhancer and a viral promoter operatively linked to a sequence that generates a therapeutic RNA, classified in class 514, subclass 44.

IV. Claims 32-42, 49, 50, 51, 58-66, 68, 76-78 drawn to a method of treatment of an animal comprising administering a viral vector comprising a myosin light chain enhancer and a viral promoter operatively linked to a sequence that generates a therapeutic RNA, classified in class 514, subclass 44.

V. Claims 43-48, 51-57, 70-75, 78-96 drawn to a method of treatment of an animal comprising administering a plasmid vector comprising a myosin light chain enhancer and a myosin heavy chain promoter operatively linked to a sequence that generates a polypeptide, classified in class 514, subclass 44.

VI. Claims 43-48, 51-57, 70-75, 78-96 drawn to a method of treatment of an animal comprising administering a viral vector comprising a myosin light chain enhancer and a myosin heavy chain promoter operatively linked to a sequence that generates a polypeptide, classified in class 514, subclass 44.

Claims 51 and 78 are generic to all groups and will be examined to the extent it encompasses the elected invention.

Claim 31 link(s) inventions I-VI. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 77. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.The inventions are distinct, each from the other because of the following reasons:

Inventions I-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to method that comprise the use of materially different vectors. Each of the groups set forth specific vector components which are different and unique from one another. Each invention thus have different functional properties and require different consideration in their administration and use in the claimed methods. Further, the use of each vector results a materially different outcome, thus a different affect in practicing the claimed method.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II-VI, restriction for examination purposes as indicated is proper.

In addition, if either groups V or VI is elected an additional election of species is required. This application contains claims directed to the following patentably distinct species of the claimed invention: Claims 43-48, 51-57, 70-75, 78-96 encompass the expression and production of any protein of interest, and specifically set forth specific unrelated proteins. If either groups V or VI is elected one specific protein set forth in the instant claims must be elected. For example, Applicants must elect α-galactosidase (claim 43), or one of the broader classes of proteins set forth as terms like enzyme, blood derivative, cytokine, growth factor, ...(claim 47).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, each of the claims not specific ally listing only one protein is generic to the invention set forth in groups V and VI.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the

limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach